

K914891 PULLER OPTION FOR ETUDE(TM)Jan 7, 1992
68 days to decisionK914891 · Product code: **FAP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k914891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Oct 31, 1991
Decision date	Jan 7, 1992
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dantec Medical, Inc.
Location	Mahwah, NJ, US
Contact	RICHARD D MANTHEI
510(k) history	25 submissions · 25 cleared · 1990-1996

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